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beet sugar juice or cane sugar juice in the production of sugar in an amount not to exceed 3.6 parts per million by weight of the raw juice.

[53 FR 39456, Oct. 7, 1988; 53 FR 49823, Dec. 9, 1988]

§ 173.75 Sorbitan monooleate.

Sorbitan monooleate may be safely used in accordance with the following prescribed conditions:

- (a) The additive is produced by the esterification of sorbitol with commercial oleic acid.
- (b) It meets the following specifications:
 - (1) Saponification number, 145-160.
 - (2) Hydroxyl number, 193-210.
- (c) The additive is used or intended for use as follows:
- (1) As an emulsifier in polymer dispersions that are used in the clarification of cane or beet sugar juice or liquor in an amount not to exceed 7.5 percent by weight in the final polymer dispersion.
- (2) The additive is used in an amount not to exceed 0.70 part per million in sugar juice and 1.4 parts per million in sugar liquor.

[51 FR 11720, Apr. 7, 1986]

Subpart B—Enzyme Preparations and Microorganisms

§173.110 Amyloglucosidase derived from Rhizopus niveus.

Amyloglucosidase enzyme product, consisting of enzyme derived from *Rhizopus niveus*, and diatomaceous silica as a carrier, may be safely used in food in accordance with the following conditions:

- (a) *Rhizopus niveus* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *niveus*.
- (b) The strain of *Rhizopus niveus* is nonpathogenic and nontoxic in man or other animals.
- (c) The enzyme is produced by a process which completely removes the organism *Rhizopus niveus* from the amyloglucosidase.
- (d) The additive is used or intended for use for degrading gelatinized starch into constituent sugars, in the production of distilled spirits and vinegar.

(e) The additive is used at a level not to exceed 0.1 percent by weight of the gelatinized starch.

§173.120 Carbohydrase and cellulase derived from Aspergillus niger.

Carbohydrase and cellulase enzyme preparation derived from *Aspergillus niger* may be safely used in food in accordance with the following prescribed conditions:

- (a) Aspergillus niger is classified as follows: Class, Deuteromycetes; order, Moniliales; family, Moniliaceae; genus, Aspergillus; species, niger.
- (b) The strain of *Aspergillus niger* is nonpathogenic and nontoxic in man or other animals.
- (c) The additive is produced by a process that completely removes the organism *Aspergillus niger* from the carbohydrase and cellulase enzyme product.
- (d) The additive is used or intended for use as follows:
- (1) For removal of visceral mass (bellies) in clam processing.
- (2) As an aid in the removal of the shell from the edible tissue in shrimp processing.
- (e) The additive is used in an amount not in excess of the minimum required to produce its intended effect.

§173.130 Carbohydrase derived from Rhizopus oryzae.

Carbohydrase from *Rhizopus oryzae* may be safely used in the production of dextrose from starch in accordance with the following prescribed conditions:

- (a) *Rhizopus oryzae* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *Rhizopus oryzae*.
- (b) The strain of *Rhizopus oryzae* is nonpathogenic and nontoxic.
- (c) The carbohydrase is produced under controlled conditions to maintain nonpathogenicity and nontoxicity, including the absence of aflatoxin.
- (d) The carbohydrase is produced by a process which completely removes the organism *Rhizopus oryzae* from the carbohydrase product.
- (e) The carbohydrase is maintained under refrigeration from production to use and is labeled to include the necessity of refrigerated storage.

§173.135 Catalase derived from Micrococcus lysodeikticus.

Bacterial catalase derived from *Micrococcus lysodeikticus* by a pure culture fermentation process may be safely used in destroying and removing hydrogen peroxide used in the manufacture of cheese, in accordance with the following conditions.

- (a) The organism *Micrococcus lysodeikticus* from which the bacterial catalase is to be derived is demonstrated to be nontoxic and nonpathogenic.
- (b) The organism *Micrococcus lysodeikticus* is removed from the bacterial catalase prior to use of the bacterial catalase.
- (c) The bacterial catalase is used in an amount not in excess of the minimum required to produce its intended effect.

§173.140 Esterase-lipase derived from Mucor miehei.

Esterase-lipase enzyme, consisting of enzyme derived from *Mucor miehei* var. *Cooney et Emerson* by a pure culture fermentation process, with maltodextrin or sweet whey as a carrier, may be safely used in food in accordance with the following conditions:

- (a) Mucor miehei var. Cooney et Emerson is classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, Mucor; species, miehei; variety Cooney et Emerson.
- (b) The strain of *Mucor miehei* var. *Cooney et Emerson* is nonpathogenic and nontoxic in man or other animals.
- (c) The enzyme is produced by a process which completely removes the organism *Mucor miehei* var. *Cooney et Emerson* from the esterase-lipase.
- (d) The enzyme is used as a flavor enhancer as defined in §170.3(o)(12).
- (e) The enzyme is used at levels not to exceed current good manufacturing practice in the following food categories: cheeses as defined in $\S170.3(n)(5)$ of this chapter; fat and oils as defined in $\S170.(3)(n)(12)$ of this chapter; and milk products as defined in $\S170.(3)(n)(31)$ of this chapter. Use of this food ingredient is limited to nonstandarized foods and those foods for which the relevant standards of identity permit such use.

(f) The enzyme is used in the minimum amount required to produce its limited technical effect.

[47 FR 28090, June 29, 1982; 48 FR 2748, Jan. 21, 1983]

§ 173.145 Alpha-Galactosidase derived from Mortierella vinaceae var. raffinoseutilizer.

The food additive alpha-galactosidase and parent mycelial microorganism *Mortierella vinaceae* var. *raffinoseutilizer* may be safely used in food in accordance with the following conditions:

- (a) The food additive is the enzyme alpha-galactosidase and the mycelia of the microorganism *Mortierella vinaceae* var. *raffinoseutilizer* which produces the enzyme.
- (b) The nonpathogenic microorganism matches American Type Culture Collection (ATCC) No. 20034,1 and is classified as follows:

Class: Phycomycetes. Order: Mucorales. Family: Mortierellaceae. Genus: *Mortierella*. Species: *vinaceae*. Variety: *raffinoseutilizer*.

- (c) The additive is used or intended for use in the production of sugar (sucrose) from sugar beets by addition as mycelial pellets to the molasses to increase the yield of sucrose, followed by removal of the spent mycelial pellets by filtration.
- (d) The enzyme removal is such that there are no enzyme or mycelial residues remaining in the finished sucrose.

[42 FR 14526, Mar. 15, 1977, as amended at 54 FR 24897, June 12, 1989]

§ 173.150 Milk-clotting enzymes, microbial.

Milk-clotting enzyme produced by pure-culture fermentation process may be safely used in the production of cheese in accordance with the following prescribed conditions:

- (a) Milk-clotting enzyme is derived from one of the following organisms by a pure-culture fermentation process:
- (1) Endothia parasitica classified as follows: Class, Ascomycetes; order,

¹Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852